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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,672	03/08/2002	Mingdong Zhou	524012000200	6586

7590 09/21/2005

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EXAMINER

AUDET, MAURY A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/980,672

Applicant(s)

ZHOU, MINGDONG

Examiner

Maury Audet

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30,37-57 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30,37-57 and 59-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

The present first action is based on the RCE filed 9/14/2005, amending the sequence list and CRF to the correct SEQ ID NO: 2 (61mer native neuregulin, rather than the mistaken 58 mer peptide previously contained therein), to which the specification otherwise contained written description for. The Notice of Allowance mailed 6/13/2005 has been vacated. Claims 30, 37-57, and 59-64 are pending. Claims 51-56 are withdrawn, as being drawn to administering *neuregulin with other agents*, a non-elected invention (See Restriction Requirement of 10/3/03, elected Group II, claims 2, 16-17, and 25-29, a method of using only neuregulin; irrespective that these claims were allowed 6/13/2005, since SEQ ID NO: 2 was previously deemed novel when incorrect in sequence list/CRF). Claims 30, 37-50, 57, and 59-64 are examined merits. The rejections/response to arguments of the Final Rejection of 3/21/2005 are maintained, based on SEQ ID NO: 2 amended to native neuregulin, the subject matter originally presented/searched. Since no new claims/arguments are presented, the present action is made FINAL.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejections of claims 30, 37-50, 57, and 59-64 under 35 U.S.C. 102(b) as being anticipated by WO 94/26298 (Cambridge Neuroscience; Sklar et al.) and Balligand et al. (Jan./Feb.), 1997; 3(4):351-360), as well as the rejection of claims 2, 16-17, and 25-27 under 35 U.S.C. 102(e) as being anticipated by Sklar et al. (US 644642 B1; Cambridge Neuroscience) and Gwynne et al. (US 6087323; Cambridge Neuroscience), are maintained for the reasons of record. Applicant's arguments have been fully considered, but are not found persuasive. In summary, Applicant argues that the references do not teach a method of using neuregulin to induce remodeling of cardiac muscle cell sarcomeric and cytoskeleton structures or cell-cell adhesions, because the references do not expressly teach the underlying bio/physiological process that neuregulin is being administered in an amount sufficient to activate the MAP kinase pathway in cardiac muscle cells (and related cascade effects). Goldman et al. (US 6,162,641) and Reh et al. (US 6,750,196) are herein cited of record merely to indicate neuregulin's known intrinsic bio/physiological effect in cardiac cells. Goldman et al. teach neuregulin's effect through the MAP kinase pathway, in a method of using neuregulin in to treat muscle tissue, specifically cardiac muscle tissue (col. 7, lines 29-34), exogenously, that acts at a receptor on a cell [i.e. cardiac muscle cell] to cause a series of biochemical alterations in the MAP kinase

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signaling pathway/cascade within a cell [i.e. cardiac muscle cell] (col. 17, lines 38-42; Example 4, col. 33, lines 49-55). Reh et al. teach that neuregulins are membrane-anchored peptide growth factors that may mediate cell-cell interactions through cell-adhesion (col. 4, lines 17-23). Thus, since the references teach the use of neuregulin for cardiac muscle regeneration and related objectives, it is intrinsic that the underlying bio/physiological processes (i.e. cell-cell adhesion stimulation) achieving these objectives are carried out through an effective amount of neuregulin to activate the MAP kinase pathway (and similarly it is deemed intrinsic that "at least  $10^{-8}$  M" is the base amount necessarily to activate said pathway); absent evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 30, 37-50, 57, and 59-64 under 35 U.S.C. 103(a) as being unpatentable over any of WO 94/26298 (Cambridge Neuroscience; Sklar et al.), Sklar et al. (US 644642 B1; Cambridge Neuroscience), Gwynne et al. (US 6087323; Cambridge Neuroscience), or Balligand et al. (Jan./Feb.), 1997; 3(4):351-360), is maintained for the reasons of record. Applicant's arguments have been fully considered, but are not found persuasive (see the discussion above, as also applicable in its entirety to the rejections under 35 U.S.C. 103).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 09/16/2005



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